COMPLAINTS AND ALLEGATIONS OF NON-COMPLIANCE PERTAINING TO HUMAN RESEARCH

1. **PURPOSE:** To establish a service level policy for any person, including patients, research participants, investigators, research, medical, and nursing staff and others to voice research-related complaints and allegations of non-compliance with institutional policies related to the human research protection program (HRPP) and Institutional Review Board (IRB) policies. Additionally, this policy:
   a. Requires investigation of all complaints and allegations;
   b. Establishes remedial action for and consequences of findings of non-compliance with HRPP and IRB policies;
   c. Identifies individuals who have responsibility for ensuring corrective action has been taken; and
   d. Includes a process for reporting to institutional officials and other appropriate parties and authorities.

   This policy ensures that all research-related complaints and allegations of non-compliance related to HRPP and IRB policies will be addressed to uphold compliance and ethical standards of human research at the Portland VA Medical Center. (PVAMC)

2. **POLICY:** Patients, research participants, investigators, research, medical, and nursing staff and others are able to voice research-related complaints and allegations of non-compliance with institutional policies related to the HRPP to the Research Service. All complaints and allegations of non-compliance pertaining to HRPP and IRB policies will be addressed promptly and initially investigated at the administrative level. The ACOS/R&D and Research Assurance & Compliance Coordinator (RACC) will evaluate the facts gathered and take appropriate action, dependent upon the nature of the events and circumstances. The responsible individuals for addressing and responding to these complaints and allegations of non-compliance pertaining to human research are identified, ensuring a response to each individual's complaint(s) and allegation(s). Remedial action and consequences will be determined for findings of non-compliance with HRPP and IRB policies and when necessary, institutional officials and other appropriate parties and authorities will be notified.

3. **RESPONSIBILITIES:**

   a. The **Associate Chief of Staff for Research & Development** is responsible for:
      (1) Developing and managing policies and procedures for individuals to voice research-related complaints and allegations of non-compliance with institutional policies related to the HRPP for research conducted at the PVAMC.
      (2) Evaluating the facts surrounding all research-related complaints and allegations of non-compliance regarding HRPP institutional policies brought forward by the RACC in consultation with the RACC.
      (3) Ensuring all research-related complaints and allegations of non-compliance regarding HRPP institutional policies brought forward by the RACC have been thoroughly investigated and, if appropriate, remedial action taken.

   b. The **Research and Development Committee (R&D)** is responsible for:
      (1) Reviewing research-related complaints and allegations of non-compliance with HRPP and IRB policies that have been brought to its attention from the RACC or IRB.
      (2) Determining and voting on recommendations for corrective action, including those forwarded by the IRB.
      (3) Documenting in the R&D Committee meeting minutes, the discussion, deliberation and final determinations for remedial action voted on by the R&D Committee.

   c. The **Institutional Review Board Chairperson** is responsible for:

(1) Notifying the RACC of any research-related complaints and allegations of non-compliance with HRPP institutional policies that have been raised by any individual.
(2) Reviewing research-related complaints and allegations of non-compliance with HRPP and IRB policies that have been brought forward from the RACC.
(3) Determining whether a special meeting of the IRB must be convened if an immediate patient safety issue is raised or if the issue can be held until the next scheduled meeting.

d. The **Institutional Review Board** is responsible for:
(1) Notifying the RACC of any research-related complaints and allegations of non-compliance with HRPP institutional policies that have been raised by any individual.
(2) Addressing any research-related complaints and allegations of non-compliance with HRPP and IRB policies raised against a principal investigator or research staff. Such allegations will be brought to the IRB by the Chair or RACC.
(3) Determining the validity of complaints and allegations brought to its attention by the RACC and making a recommendation for remedial action.
(4) Documenting in the IRB meeting minutes, the discussion, deliberation and final recommendation to the R&D Committee.

e. **Research Assurance and Compliance Coordinator** is responsible for:
(1) Being the primary contact person and documenting all research-related complaints and allegations of non-compliance with HRPP and IRB policies.
(2) Maintaining a log and associated documentation of all research-related complaints and allegations of non-compliance with HRPP and IRB policies.
(3) Conducting an initial review, as appropriate to the nature of the complaint or allegation, of all research-related complaints and allegations of non-compliance with HRPP and IRB policies.
(4) Notifying the ACOS/R&D of any incident that has arisen and that an inquiry has begun.
(5) Evaluating the facts gathered in consultation with the ACOS/R&D and taking appropriate action.
(6) Forwarding non-frivolous research-related complaints and allegations of non-compliance with HRPP and IRB policies received to the appropriate individuals and committees.
(7) Ensuring that all complaints and allegations of non-compliance with HRPP and IRB policies have been addressed.

f**.** **Principal Investigators** are responsible for:
(1) Notifying the RACC of any research-related complaints and allegations of non-compliance with HRPP institutional policies that have been raised by any individual.
(2) Immediately providing all information requested by the RACC to address any complaints and allegations of non-compliance with HRPP and IRB policies.
(3) Complying with decisions made by the IRB and R&D Committee regarding findings of non-compliance.

g. **Medical Center and Research Staff** are responsible for:
(1) Notifying the RACC of any research-related complaints and allegations of non-compliance with HRPP institutional policies that have been raised by any individual.
(2) Immediately providing all information requested by the RACC to address any complaints and allegations of non-compliance with HRPP and IRB policies.
(3) Complying with decisions made by the IRB and R&D Committee regarding findings of non-compliance.

4. **DEFINITION:**

a. **Frivolous complaint or allegation**: A complaint or allegation may be considered frivolous if the following two elements are met:
   (1) The case is not an immediate threat to patient safety; and
   (2) Upon initial review, none of the presented information is accurate or appears to be either accurate or verifiable.

   E.g. In some cases, there may be a misunderstanding about the study that can be resolved immediately. If so, the complaint and the information provided to resolve the complaint should be documented with the RACC.

5. **PROCEDURES:**
   a. **Patients, research participants, investigators, research, medical and nursing staff, and others are informed of their ability and responsibility to report and/or voice any research-related complaints and allegations of non-compliance with HRPP and IRB policies according to the following procedures:**
      (1) **Study participants**
      Every participant in a research study for which informed consent is required as determined by the IRB at the Portland VAMC receives a copy of the corresponding study's consent form, which contains the following:
         (a) encouragement to contact the IRB Chair to discuss any issues to their research study participation; and
         (b) an explanation regarding whom to contact for three specific situations:
            i. For answers to pertinent questions about the research;
            ii. For answers to questions about subjects' rights (the subject is encouraged to contact the Chair of the IRB through the Research Service); and
            iii. In the event of a research-related injury.

      (2) **Medical Center and Research staff**
      Every six months an e-mail will be sent through VISTA and MS Outlook to all Medical Center and research staff regarding who to contact and how to report any research-related complaints and allegations of non-compliance with HRPP and IRB policies.

      (3) This policy will also be presented as an agenda item at a Medical Staff Meeting and will be discussed at meetings of individual services (such as nursing and pharmacy).

   b. **Notifying the Research Assurance & Compliance Coordinator (RACC)**
      (1) All research-related complaints and allegations of non-compliance with HRPP and IRB policies should be reported directly to the RACC.
      (2) The RACC may be contacted according to the following:
         (a) Mail: Angela Lacey
         Research Assurance & Compliance Coordinator
         Department of Veterans Affairs
         Medical Center/Portland Division
         Research & Development Service
         3710 S.W. U.S. Veterans Hospital Road
         Portland, OR 97239
         (b) Phone: 503.220.8262 ext. 51165
         (c) Fax: 503.273.5351
         (d) e-mail: Vista: **G.RESEARCH FEEDBACK**
         Outlook: **research.feedback@med.va.gov**
      (3) An individual's identity will be kept confidential, unless it is pertinent to the investigation, when voicing research-related complaints and allegations of non-compliance pertaining to human research to protect their rights.
      (4) Anonymous research-related complaint(s) and allegation(s) may also be left by voice mail at: 503.220.8262 ext. 51165.

(5) The RACC will reassure the individual that all means will be taken to inquire into the circumstances and appropriate measures will be taken to address the issue.

c. **Research Assurance & Compliance Coordinator**

The RACC must adhere to the following procedures:

(1) Review all research-related complaints, and allegations of non-compliance with HRPP and IRB policies.

(2) Document all research-related complaints and allegations of non-compliance with HRPP and IRB policies in the R&D Service "Complaints and Allegations of Non-Compliance in Human Research Institutional Policies Log." The minimum information to be documented will include the individual's name, address, and phone number, unless it is anonymous; study protocol title; Principal Investigator's name; dates; summary of the complaint or allegation.

(3) Conduct an initial review, as appropriate to the nature of the complaint or allegation, of all research-related complaints and allegations of non-compliance with HRPP and IRB policies.

(4) Notify the ACOS/R&D of any incident that has arisen and that an inquiry has begun.

(5) Evaluate the facts gathered in consultation with the ACOS/R&D and take appropriate action. If an immediate patient safety issue is raised, the IRB Chair will be immediately notified. In these cases, the IRB Chair will need to determine whether a special meeting of the IRB must be convened or if the issue can be held until the next scheduled meeting.

(6) Notify the appropriate Principal Investigator(s) and any other involved individuals, regarding a complaint and allegations of non-compliance, involving the respective party(ies), regardless of whether or not the complaint or allegation is frivolous.

(7) Notify the IRB of any non-frivolous complaints and allegations of non-compliance pertaining to HRPP and IRB policies.

(8) Notify the R&D Committee Chair of any non-frivolous complaints and allegations of non-compliance pertaining to HRPP and IRB policies, regarding the IRB.

(9) Non-frivolous complaints and allegations of non-compliance pertaining to HRPP and IRB policies regarding the R&D Committee will be handled by the ACOS/R&D.

(10) Document and file all actions and correspondence regarding research-related complaints and allegations of non-compliance with HRPP and IRB policies.

(11) Assist in the collection of all necessary background data to allow for a full investigation by the IRB and/or R&D Committee, as necessary.

(12) Ensure that all research-related complaints and allegations of non-compliance with HRPP and IRB policies are addressed appropriately.

d. **Investigation of Complaints and Allegations of Non-compliance**

(1) Complaints and allegations of non-compliance will be first reviewed at the administrative level by the RACC in consultation with the ACOS/R&D and IRB Chair in order to maintain the confidentiality of individuals involved in the complaint and allegation in the event that a complaint or allegation may be frivolous.

(2) Non-frivolous complaints regarding a specific study, investigator, and/or study staff will be addressed by the IRB and any recommendation for corrective action forwarded to the R&D Committee.

(3) Non-frivolous complaints involving the IRB and/or member(s) will be addressed by the R&D Committee.

(4) Non-frivolous complaints involving the R&D Committee and/or member(s) will be addressed by the ACOS/R&D.

e. **Determination for Remedial Action**

(1) If an issue involves human subject protection and safety, immediate action will be taken to minimize potential harm to subjects or staff pending the outcome of a formal review.

(2) Dependent upon the nature of the event or circumstances, any of the following actions may occur:
  (a) Further inquiry may be initiated;
  (b) Administrative action may be taken;
  (c) Details and recommendations forwarded to the appropriate committee Chairpersons (IRB and R&D Committee) for consideration in their committees and action;
  (d) Details and recommendations forwarded to the Chief of Staff and/or the Medical Center Director for action;
  (e) Details and recommendations forwarded to the appropriate officials at affiliated institutions for notification, action, and/or follow-up;
  (f) Other actions as deemed appropriate.

(3) If an active research project is found in non-compliance with HRPP and IRB policies, the IRB, either in a regularly scheduled or specially convened meeting, will determine whether or not a research project:
  (a) May continue;
  (b) May continue with modifications;
  (c) May be suspended; or
  (d) May be terminated.

(4) If an active research project is found in non-compliance with HRPP and IRB policies, a recommendation will be made as to whether or not a Principal Investigator or anyone involved with the research project:
  (a) May continue conducting research;
  (b) May continue conducting research with modifications; or
  (c) May be suspended from conducting research.

(5) For complaints and allegations of non-compliance with HRPP and IRB policies regarding the IRB and/or member(s), policies and procedures will be reviewed by the IRB and recommendations to prevent this issue from arising in the future will be forwarded to the R&D Committee.

(6) For complaints and allegations of non-compliance with HRPP and IRB policies, involving the R&D Committee and/or member(s), policies and procedures, will be reviewed by the ACOS/R&D and action taken to prevent this issue from arising in the future.

f. **Notification**

(1) The RACC, through the ACOS/R&D, will notify in writing all previously contacted individuals describing the decision(s) made and action(s) taken regarding the research-related complaints and allegations of non-compliance related to HRPP and IRB policies.

(2) Any individual voicing an anonymous research-related complaint or allegation will not be notified of the decision(s) made and action(s) taken regarding the complaint(s) or allegation(s) by virtue of being anonymous.

(3) If an allegation or complaint is determined to be frivolous, the IRB and R&D Committee will be notified of the frivolous allegation or complaint, but the information presented will be stripped of all identifiers.

g. **Reports to Institutional Officials and other Appropriate Parties and Authorities**

The final course of action regarding the complaint or allegation is entirely dependant upon the nature, severity, and degree of seriousness of the findings. As described in this policy, all actions taken will be at the institutional level most appropriate for the circumstances. All actions requiring reporting to regulatory bodies outside the medical center, such as the Office of Research Oversight (aka the Office of Research Compliance & Assurance (ORCA)), Office for Human Research Protection (OHRP), and/or if investigational devices or drugs are involved the Food and

Drug Administration (FDA), will be made by the IRB Chair or ACOS/R&D at the request of the Medical Center Director as Institutional Official for the Human Research Protection Program. Instances, which may require such notification, at the discretion of the Research & Development Committee include:

(1) findings of serious or continuing noncompliance with the regulations for the protection of human subjects or with the requirements of the IRB;
(2) any unanticipated problems involving risks to subjects or others (e.g. death of healthy volunteers participating in research);
(3) suspension or termination of IRB approval (e.g. associated with unexpected harm, research not being conducted in accordance with the IRB's requirements).

5. REFERENCES: 38CFR16.103(b)(5)
38CFR16.116(a)(7)
M-3, Part I, Chapter 9, Appendix 9C
45CFR46.103(b)(5)
45CFR46.116(a)(7)
21CFR50.25(a)(7)
National Committee for Quality Assurance Standards

6. CONCURRENCES: Endorsed by the Research & Development Committee 11/24/2003.

7. RESCISSION: HRPP: Policy & Procedure No. 3, Endorsed by the R&D Committee 05/19/2003.

8. FOLLOW-UP RESPONSIBILITY: ACOS, Research & Development Service (R&D)

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ACOS, Research & Development Service